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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,587	12/04/2001	Michael A. Tainsky	0788.00063	5172

7590

05/19/2005

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EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/004,587	<b>Applicant(s)</b> TAINSKY ET AL.	
	<b>Examiner</b> Lori A. Clow, Ph.D.	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 10-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Applicants' arguments, filed 16 February 2005, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-19 are currently pending. This application contains claims 1-6 and 10-19 drawn to an invention nonelected with traverse in the reply filed 26 April 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 1-6 and 10-19 remain withdrawn.

### **Information Disclosure Statement**

It is noted that the Information Disclosure Statement filed 8 August 2003 was only partially considered, as stated in the Office Action of 12 July 2004. The following references were not considered because they were missing from the file: Berek (1991); Buettner (1993); Kohonen (1995); and Poggio (1990). Applicant was kindly requested to send these references with the next response. The references noted above still have not been received.

### **Oath**

The Oath filed 12 October 2004 is acknowledged.

### **Claim Rejections - 35 USC § 112-1<sup>st</sup> Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 7 recites “by comparing the markers obtained by said differentially biopanning step to an array of known markers of disease”. There is no apparent support in the instant specification, nor has any been provided, for this limitation.

Claim 9 recites “constructing a classifier using data from a template”. There is no apparent support in the instant specification, nor has any been provided, for this limitation.

Claims 7-9 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth in the Previous Office Action.

#### **Claim Rejections - 35 USC § 112-2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 has been amended to recite “constructing a classifier using data from a template”. It is unclear what template is intended, as the template is not defined in the specification as filed.

### **Response to Applicant's Arguments**

Applicant argues the following:

1. “The claims have been amended to more specifically recite that differential biopanning occurs between a control sera or a test sera and the patient's sera. This is done to selectively biopan for markers of disease”. Applicant points to page 25, line 5 to page 26, line 21 for support. This is not persuasive. The Examiner maintains that the specification provides a definition for “biopanning” at page 16. Biopanning is defined, as it is in the art, as “a selection process for use in screening a library”. “Biopanning is carried out by incubating phages encoding the peptides with a plate coated with proteins, washing away the unbound phage, eluting, and amplifying the specifically bound phage. As is clear from the definition and from the specification details, biopanning involves exposing sera to a library and not exposing sera to sera, as is recited in the instant claims.

2. “The portion of the specification refers to above provides details with regard to how the markers are identified. More specifically, the markers are identified because they are present in the cancer patients versus healthy sera”. This is not persuasive. Nowhere in the instant claims provides sera from cancer patients compared to sera from normal patients, as suggested by

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Applicant. In the second step of claim 7, one is to determine if markers are included among cDNA clones indicative of disease. How does one know if the clones are indicative of disease? Did they come from a tumor library, for instance? Where do the markers come from? There are no previous steps of marker determination, only of biopanning sera. The Examiner maintains that the guidance in the specification identifies epitopes which are reactive to antibodies, which could conceivably be the markers intended for detection, but this is not clear. The claims are not directed to such identification and detection of antibodies. Furthermore, the instant claims do not provide for a phage library in which the expressed genes are from known tumors or cell lines. Without known phage libraries, how can one identify specific markers? How does one determine if markers are present among cDNA clones, when the markers are not known? Where do the markers come from? Are they pre-determined to be associated with a certain disease state? How are the markers identified?

3. Applicant argues that the “presently claimed invention provides a method of creating an array of markers or a combination of markers”. This is not persuasive, as there are no such limitations of array creation in the instant claims.

4. Applicant argues that “the determination of epitopes that are indicative of cancer can be automated”. Applicant has pointed to page 30 for support. The Examiner maintains that the specification does not provide enablement for how markers are to be determined by automatic analysis? How are markers determined by software without any physical assay indication of the presence of a marker? How are classifiers constructed for this analysis? There is no guidance in the specification as to how classifiers for markers detection are indicated.

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### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the

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USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

May 12, 2005  
Lori A. Clow, Ph.D.  
Art Unit 1631  
*Lori A. Clow*

*Marjorie A. Moran*  
5/12/05

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**